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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,034	04/23/2001	Gerardo Castillo	PROTEO.P07CI3	4033

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09/03/2002

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,034

Applicant(s)

CASTILLO ET AL.

Examiner

Cybille Delacroix-Muirheid

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,6,8-11,13,16,17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,6,8-11,13,16,17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other:

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DETAILED ACTION

The following is responsive to Applicant's response via telephone dated March 19, 2002.

Claims 5, 7, 14, 15 are cancelled without prejudice or disclaimer.

In view of new art obtained in an update search, the finality of the action mailed Dec. 19, 2001 is withdrawn.

The indicated allowability of claims 2, 3, 6, 8-11, 13, 16, 17, 19 is withdrawn in view of the newly discovered reference(s) to Womack 5,730,988 and Castillo et al., 6,264,994. Rejections based on the newly cited reference(s) follow.

Claims 2, 3, 6, 8-11, 13, 16, 17, 19 are currently pending.

Information Disclosure Statement

Applicant's Information Disclosure Statement received Feb. 11, 2002 has been considered.

Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Objections

1. Applicant is advised that should claims 8, 16 and 17, 19 be found allowable, claims 8 and 16 as well as 17 and 19 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

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one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 8, 16 and 17, 19 are identical in scope because both claims 8 and 16 recite a method for treating an amyloid disease in a patient comprising administering effective amounts of plant matter from *Uncaria tomentosa* and either selenium, folic acid or vitamin B12. The same applies to claims 17 and 19 which recite a pharmacological agent comprising effective amounts of *Uncaria tomentosa* and either selenium, folic acid or vitamin B12.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 8, 9, 16, 17, 2, 6, 19, 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Womack 5,730,988. wtg

Womack discloses a method of treating persons suffering from diabetes by administering nutritional compositions (drink or capsule) comprising 500 mg of Cat's claw (*Uncaria tomentosa*) in combination with Folic Acid, Selenium, Vitamin B1. Please see the abstract; col. 2, line 66 to col. 3, line 5; Example 1, "Phase II"; col. 8, lines 15-20.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 8-11, 17, 2, 3, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Womack, supra.

Womack as applied above.

Womack does not specifically disclose a nutritional supplement containing ginseng or gotu kola in combination with the Cat's claw; however, the Examiner turns to col. 7, line 63 to col. 8, line 7, where Womack teaches that herbal agents such as gotu kola and ginseng may be included in the nutritional supplements because they are effective against symptoms such as high blood pressure which occurs in persons with diabetes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the nutritional supplements containing Cat's claw to additionally include gotu kola or ginseng because, in view of Womack's teaching, one of ordinary skill in the art would reasonably expect these herbal agents to treat symptoms which accompany diabetes such as high blood pressure. Such a modification would have been motivated by the reasoned expectation of producing a nutritional composition which is effective in comprehensively treating persons suffering from diabetes.

With respect to claims 3, which recites a dosage amount of *Uncaria tomentosa*, since the prior art has established that the efficacy of Cat's claw (*Uncaria tomentosa*) is dependent upon its dosage amount, it would have been obvious to one of ordinary skill in the art to further modify the method and composition of Womack such that the Cat's claw is present in an amount which is effective to optimize its therapeutic effect.

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Concerning claims 10-11 which recite other modes of administration, i.e. aerosol spray or parenteral administration, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them in the teachings of the prior art.

Moreover, modification of the compositions and method of Womack to include additional antioxidants such as Echinacea or Vitamin E and additionally vitamins such as Vitamin B12, niacin or nicotinate would have been obvious to one of ordinary skill in the art in view of Womack's teaching that the presence of an antioxidant would serve to enhance metabolism and facilitate regeneration of damaged nerves and further that it would be beneficial for the compositions to include vitamins. Please see col. 5, lines 65-67; col. 6, lines 60-65. Such a modification would have been motivated by the reasoned expectation of producing a nutritional composition having therapeutic/beneficial antioxidant and nutritional properties.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 17, 2, 3, 6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 14-18 of U.S. Patent No. 6,264,994. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN '994 claim a composition comprising an amount of plant matter from *Uncaria tomentosa* (cat's claw) and an amount of ginko biloba and gotu kola.

The difference between the instant application and USPN '994 is that USPN '994 broadly claims a "composition" which may have pharmaceutical use (see dependent claim 18), whereas the claims of the instant application recite a "pharmacological agent" comprising effective amounts of cat's claw and ginko biloba or gotu kola.

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However, the scope of the claims of the instant application and the claims of USPN '994 overlap because at least 2 of the substances present in the compositions are identical. Additionally, the broader compositions claims of USPN '994 encompass the more specific pharmaceutical compositions of the instant application.

Conclusion

Claims 2, 3, 6, 8-11, 13, 16, 17, 19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM



Aug. 30, 2002

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

